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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,797	10/01/1999	STEVE A. HERWECK	ATA-257	8813

959 7590 10/24/2002

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/411,797

Applicant(s)

HERWECK ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 44-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6-20, 24-27 and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Valli, 4,437,856.

Valli discloses a member (11) constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration, wherein the wall of the member includes at least one microporous portion of micro-channels (11') formed by microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through micro-channels substantially controlling the permeation of fluid through the wall, see column 3, lines 36-39. The area between the orifices (11') constitute the nodes.

Moreover, the nodes are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall.

The nodes are considered to be oriented substantially perpendicular to the longitudinal axis of the member.

The micro-channels (11') within the microporous portion of the wall are sized to permit the fluid to pass from the inner surface to the outer surface of the wall.

The size of the micro-channels varies longitudinally, and circumferentially, see Figure 2.

The member has a unitary construction of generally homogenous material.  
The fluid includes a medicinal agent.

The device is capable of delivering thrombolytics.

The microporous portion of the wall is considered to border a second portion of the wall that is generally impermeable to the pressurized fluid. Portion of the wall that does not have hole (11') is considered the second portion of the wall as claimed.

As to claim 11, it is inherent that the member deploys to the second configuration upon application of a fluid having a pressure of approximately 1 psi to 250 psi.

As to claim 12, it is inherent that the porosity is sufficient to allow fluid to pass therethrough at a flow rate of approximately 0.01 ml/min to 100 ml/min.

As to claims 17, 19 and 20, the wall further includes a second microporous portion having a porosity sufficient for the fluid to permeate through the wall, see column 3, lines 36-39.

As to claim 18, an impermeable portion of the wall is considered interposed between the microporous portion and the second microporous portion.

As to claim 24, the microporous portion is considered to have a hydraulic conductivity less than the hydraulic conductivity of the body vessel.

As to claim 45, a first layer of biocompatible material is disclosed at (2)

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And a second layer of biocompatible material is disclosed at (11).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-27 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valli, 4,437,856, in view of Butler et al., 5,843,069.

Valli discloses the invention except for the member being constructed of fluoropolymer material.

Butler et al. discloses a the wall of the fluid delivery device constructed of a biocompatible fluoropolymer material, see column 14, line 5.

Claims 5, 21-23, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valli, 4,437,856

Valli discloses the invention substantially as claimed, see above. However, Valli does not disclose the specific internodal distance, nor the hydraulic conductivity as claimed.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Valli device to have an internodal distance or

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hydraulic conductivity as claimed by Applicant since such modifications would not depart from the scope of the invention, see column 5, lines 56-61.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.

October 21, 2002

ANHTUAN T. NGUYEN  
PRIMARY EXAMINER

10/21/02